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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,701

Applicant(s)

SU ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I and species nucleic acids, nucleotides, etc., drawn to claims 1-3, 5-26 in the reply filed on May 16, 2006 is acknowledged. Claims 4 and 27-34 are withdrawn as drawn to non-elected Groups or species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Interpretation

2. The claims as written clearly indicate that the "tag" can be anything from a nucleic acid or nucleotide to a fluorescent dye. Therefore, two different prior art rejections to address two of the possibilities will be made. Singer teaches Raman tags or fluorescent dyes and Urdea teaches nucleotides.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5 and 8-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Singer et al (U.S. Patent 6,534,266).

Singer teaches a method of claims 1 and 12 comprising:

- (a) obtaining a barcode comprising two or more tags attached to an organic molecule backbone (see column 8, lines 6-38, where oligonucleotides have five different fluorophores attached to the nucleic acid probe backbone to form a barcode),
- (b) binding the barcode to a target (see column 8, lines 39-43, where the probes are hybridized to a target),
- (c) detecting the barcode bound to the target (see column 8, lines 44-57, where the barcodes are individually detected).

With regard to claims 2-3, Singer teaches single stranded nucleic acid probes (see column 8, lines 16-38, where the oligonucleotides were synthesized, which necessarily is single stranded).

With regard to claim 5, Singer teaches the use of a variety of fluorescent dyes such as Cy3, Cy5, etc (see column 3, lines 1-2, where these dyes are, of course, fluorescent dyes, but also will function as Raman tags).

With regard to claim 8, Singer teaches detection with fluorescence spectroscopy (see column 9, lines 5-20).

With regard to claim 9, Singer teaches that the barcode binds via the oligonucleotide probe (see column 8, lines 39-43).

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With regard to claim 10, Singer teaches that distinguishable barcodes can be generated using multiple copies of the same tag (see column 3, line 59 to column 4, line 6).

With regard to claims 11, 13, 14, 25, 26, Singer teaches a nucleic acid target and detection of the binding to the target (see column 8, lines 39-57).

With regard to claim 15, Singer teaches forming a polymer using monomeric units (see column 8, lines 16-37, where the oligonucleotide synthesizer forms a polymer of nucleotide monomers).

With regard to claims 16-17, Singer teaches monomeric units which comprise different raman tags (see column 3, lines 1-2, where these dyes are, of course, fluorescent dyes, but also will function as Raman tags and see column 8, lines 16-19).

With regard to claims 18, 20, Singer teaches attachment by an amino group, which is a spacer, after the standard commercial oligonucleotide synthesizer step of deprotection (see column 8, lines 32-34).

With regard to claims 19, 24, Singer teaches attachment after polymerization of the monomeric unit (see column 8, lines 32-38).

With regard to claim 21, Singer teaches formation of 31 different subsequences (see column 8, lines 16-32).

With regard to claims 22-23, Singer teaches formation of the oligonucleotide using automated DNA synthesizers, which inherently utilize bead based solid supports (see column 8, lines 32-35).

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5. Claims 1-3, 5-7 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Urdea et al (U.S. Patent 5,635,352).

Urdea teaches a method of claims 1 and 12 comprising:

- (a) obtaining a barcode comprising two or more tags attached to an organic molecule backbone (see figure 11 and column 20, line 35 to column 21, line 49, where the AMP or comb probe is formed by the attachment of branches of nucleotides, and where 14 different tags are attached to the nucleic acid backbone (see column 20, line 38, specifically)),
- (b) binding the barcode to a target (see figure 11 and column 21, line 50 to column 22, line 7, where the probes are hybridized to a target),
- (c) detecting the barcode bound to the target (see figure 11 and column 22, lines 8-20, where the barcodes are detected).

With regard to claims 2-3, Urdea teaches single stranded nucleic acid probes (see figure 11 and column 20, line 35 to column 21, line 37, where the oligonucleotides were synthesized, and shown as single stranded).

With regard to claim 5, Urdea teaches the use of nucleotide tags which are detected (see figure 11 and columns 20-22).

With regard to claims 6-7, Urdea teaches branched nucleic acids with branches located at predetermined sites along the backbone (see figure 11 and column 20, line 35 to column 21, line 40).

With regard to claim 9, Urdea teaches that the barcode binds via the oligonucleotide probe (see figure 11 and column 21, line 50 to column 22, line 7).

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With regard to claim 10, Urdea teaches that distinguishable barcodes can be generated using multiple copies of the same tag (see figure 13, where binding of AMP 1 and AMP2 can be distinguished by LP1 and LP2).

With regard to claims 11, 13, 14, Urdea teaches a nucleic acid target and detection of the binding to the target (see figures 11 and 13 and column 21, line 50 to column 22, line 7).

With regard to claim 12, Urdea teaches a “container” and “probe section” where the tagged LP1 and LP2 probes are hybridized to the AMP probes to create a barcode (see figure 13).

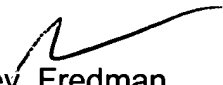
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

6/16/06